PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO	Complete if Known		
INFORMATION DISCLOSURE	Application Number	10/660,893	
STATEMENT BY APPLICANT	Filing Date	September 12, 2003	
	First Named Inventor	Charles Link	
(use or many shoots or program)	Group Art Unit	1645 1636	
(use as many sheets as necessary)	Examiner Name	Not Yet Assigned Dunston	
Sheet 1 of 8 6	Attorney Docket Number	05237.0003.CPUS01	

		U.S. F	ATENT DOCU	IMENTS	
Examiner Initials*	Cite No. ¹	Document Number Number - Kind Code ² (if known)			Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
JD	A1	US-4,683,195	07-28-1987	Mullis	
	A2	US-5,364,783	11-15-1994	Ruley	
	A3	US-5,565,350	05-05-1998	Kmiec et al.	
	A4	US-5,922,601	07-13-1999	Baetscher	,
	A5	US-6,130,313	10-10-2000	Li	
	A6	US-5,928,888	07-27-1999	Whitney	
	A7	2002/0025940 A1	02-28-2002	Whitney	
	A8	US-6,096,717	08-01-2000	Jarvik	
V	A9	US-6,498,013 B1	12-24-2002	Velculescu	
JD	A10	US-6,080,576	06-27-2000	Zambrowicz	

	FOREIGN PATENT DOCUMENTS						
		Foreign Patent Document			Pages, Columns, Lines, Where Relevant Passages or Relevant		
Examiner Initials*	Cite No. 1	Country Code ³ –Number ⁴ – Kind Code ³ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Figures Appear	Té	
JD	Bl	WO 98/53319	11-26-98	Vogelstein			
'ID	B2	WO 99/02719	01-21-99	Christopher			
	B3		00-03-25	Massachusetts Institute of			
ம		WO 0056874 A	L	Technology	<u> </u>		

Examiner	/Jennifer Dunston/ (10/19/2006)	Date	
Signature		Considered	

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Substitute for form 1449B/PTO			Complet	e if Known
INI	FORMATION D	ISCLOSURE	Application Number	10/660,893
STATEMENT BY APPLICANT			Filing Date	September 12, 2003
			First Named Inventor	Charles Link
· · · · ·			Group Art Unit	1645 1636
(use	as many sheets as nec	cessary)	Examiner Name	Yet to Be Assigned Dunston
Sheet	2 of /	3 6	Attorney Docket Number	05237.0003.CPUS01

			OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENT	S
	miner ials*	Cite No. 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher city and/or country where published	T²
J	Ð	C1	Altschul et al. (1997). Gapped BLAST and PSI_BLAST: a new generation of protein database search programs. Nucleic Acids Res. 25: 3389-3402	
	C2 Armentano et al. (1987). Effect of Internal Viral Sequences on the Utility of Retroviral Vectors. J. Virol. 61: 1647-1650			
		C3	Bender et al. (1987). Evidence that the Packaging Signal of Moleney Murine Leukemia Virus Extends into the gag Region. J. Virol. 61: 1639-1649	
		C4	Claverie and States (1993). Information Enhancement Methods for Large Scale Sequence Analysis. Comput. Chem. 17: 191-201	
		C5	Cormier et al. (1974). Bioluminescence in Coelenterates. Biochem. Biophys. Acta 346: 137-164	
		C6	Corpet et al. (1988). Multiple Sequence Alignment with Hierarchical Clustering. Nucleic Acid Res. 16: 10881-90	
		C7	Costa et al. (1998). Transcriptional regulation of the tissue –type plasminogen activator gene in human endothelial cells: identification of nuclear factors that recognize functional elements in the tissue-type plasminogen activator gene promoter. European Journal of Biochemistry 258: 123-131	
		C8	Henikoff and Henikoff (1992). Amino acid Substitution Matrices From Protein Blocks. Proc. Natl. Acad. Sci. USA 89: 10915	
	/	C9	Higgins and Sharp (1988). Clustal: a package for performing multiple sequence alignment on a microcomputer. Gene 73: 237-244	
J	סח	C10	Higgins and Sharp (1989). Fast and sensitive multiple sequence alignments on a microcomputer. CABIOS 5: 151-153	

Examiner	/Jennifer Dunston/ (10/19/2006)	Date
Signature	/ definities Danscon/ (10/15/2000)	Considered

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Sub	stitute for form 1449B/PTO	Complet	e if Known
IN	FORMATION DISCLOSURE	Application Number	10/660,893
STATEMENT BY APPLICANT		Filing Date	September 12, 2003
		First Named Inventor	Charles Link
(use as many sheets as necessary)		Group Art Unit	1645 1636
		Examiner Name	Yet to Be Assigned Dunsto
Sheet	3 of \$\mathcal{Z}\$ 6	Attorney Docket Number	05237.0003.CPUS01

		C11	The human same consertium (2001) Initial acquencing and	
J	D		The human gene consortium. (2001). Initial sequencing and	
-	<u> </u>		analysis of the human genome. Nature 409: 860-921	
		C12	Huang et al. (1992). Parallelization of a local similarity	X
,			algorithm. Computer Applications in the Biosciences 8: 155-	•
	65			
[]		C13		
			the Long Terminal Repeat of a Self Inactivating Vector Results in	
			High-Titer Retroviral Vectors With Tissue Specific Expression.	
			Human Gene Therapy 9: 2459-2468	
	·	C14		i
	3		Green Fluorescent Protein During Early Murine Embryonic	
			Development. FEBS Letters 440: 370-376	*
		C15	Fraser et al. (1997). Strategies for whole microbial genome	
			sequencing and analysis. Electrophoresis 18: 1207-1216	
	C16 Goeddel et al. (1980). Nucleic Acid Res. 8: 4057			
		C17		
			abundance in yeast. Molecular and Cellular Biology: 1720-	
			1720	
		C18	Larison et al. (1995). Use of a New Fluorogenic Phosphatase	
			Substrate in Immunohistochemical Applications. J. Histochem.	
			Cytochem. 43: 77-83	
		C19	Lidberg et al. (1998). Transcriptional Regulation of Human	
			Carboxyl Ester Lipase Gene in Exocrine Pancreas. The Journal	
			of Biological Chemistry 273: 47	
		C20	Meyers and Miller (1988). Optimal alignments in linear space.	
			Computer Applic. Biol. Sci. 4: 11-17	
		C21	Miller et al. (1989). Improved retroviral vectors for gene transfer	
	,		and expression. Biotechniques 7: 980-990	
$\Box A$		C22	Needleman and Wunsch (1970). A general method applicable to	
_	n		the search for similarities in the amino acid sequence of two	
J	ט		proteins. J. Mol. Biol. 48: 443	

Examiner		Date	
Signature	/Jennifer Dunston/ (10/19/2006)	Considered	

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IN	FORMATIO	N DISCLOSURE	Application Number	10/660,893
STATEMENT BY APPLICANT			Filing Date	September 12, 2003
			First Named Inventor	Charles Link
			Group Art Unit	1645 1636
(use	as many sheets a	s necessary)	Examiner Name	Yet to Be Assigned Dunsto
Sheet	4 of	6 کتر ا	Attorney Docket Number	05237.0003.CPUS01

١,	D C	C23		
٦	עי		retroviral vector system for gene delivery to mammalian cells. J.	1
			of Virology 70: 62-67	
	•	C24	Pearson and Lipman (1988). Improved tools for biological	
			sequence comparison. Proc. Natl. Acad. Sci. 85: 2444	
П		C25	Person et al. (1994). Using the FATSA program to search protein	
	and DNA sequence databases. Methods in Molecular Biology			
			24: 307-331	
		C26	Post et al. (1981). Regulation of α genes of herpes simplex virus:	
	i.		expression of chimeric genes produced by fusion of thymidine	
	:. :;		kinase with α gene promoters. Cell 24: 555-565	•
H		C27	Smith and Waterman (1981). Comparison of biosequences. Adv.	
			Appl. Math. 2: 482	
		C28	Shimatake et al. (1981). Purified χ regulatory protein CII	
	positively activates promoters for lysogenic development.			
	.		Nature 292: 128	
		C29	Igarashi et. al. (1998). A Novel Strategy of Cell Targeting Based	÷ .
			on Tissue-Specific Expression of the Ecotopic Retrovirus	
			Expression Gene. Human Gene Therapy 9: 2691-2698	
		C30	Valerie et al. (1998). Tissue Specific Cell Cycle Regulated	
			Chimeric Transcription Factors for the Targeting of Gene	
	l		Expression to Tumor Cells. Human Gene Therapy 9: 2653-	0
			2659 Jerome et al. 90	
		C31	Medico et al (2001). A gene trap vector system for identifying	
			transcriptionally responsive genes. Nature Biotech. 19: 579.	
		C32	Wooten and Federhen (1993). Comput. Chem. 17: 149-163	
V	C33 Young and Link (2000). Chimeric Retroviral Helper Virus and			
_	_		Picomavirus IRES Sequence to Eliminate DNA Methylation for	
J	ן סח		Improved Retroviral Packaging Cells. J. Virol. 74(11): 5242-	
			5249	·

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Signature	/Jennifer Dunston/ (10/19/2006)	Considered	

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Substitute for form 1449B/PTO				Complet	e if Known
INFORMATION DISCLOSURE			DISCLOSURE	Application Number	10/660,893
STATEMENT BY APPLICANT			Filing Date	September 12, 2003	
	UZIRZBIVIZI Z II.Z ZZCIZI			First Named Inventor	Charles Link
			on account)	Group Art Unit	1645 1636
(use as many sheets as necessary)		Examiner Name	Yet to Be Assigned Dunston		
Sheet	5	of	\$ 6	Attorney Docket Number	05237.0003.CPUS01

		C34		
J	TD		Human Carnitine Palmitoyltransferase IB Gene Promoter by Fatty	
Ι,			Acid Enzyme Substrate. The Journal of Biological Chemistry	
\vdash		C35	Whitney at al (1908) A geneme wide functional agent of signal	
		(33	Whitney et al (1998) A genome-wide functional assay of signal transduction in living mammalian cells. Nature Biotechnology	
			16:1329	
П		C36	Jarvik et al (1996). CD-Tagging: A new approach to gene and	·
			protein discovery and analysis. BioTechniques 20: 896-904	
		C37	Skarnes et al (1995). Capturing genes encoding membrane and	
	:		secreted proteins important for mouse development. Proc. Natl.	
			Acad. Sci USA 92: 6592	
		C38	1	
			of 2000 genes in mouse embryonic stem cells. Nature 392: 608-	
-		COO	611.	· · · · · · · · · · · · · · · · · · ·
		C39	European Search Report, dated April 2, 2004	
	:	C40	Brenner, et al. (1989). Analysis of mammalian cell genetic	٠
			regulation in situ by using retrovirus-derived 'portable exons'	,
			carring the Escherichia coli lacZ gene," Proc. Natl. Acad. Sci, Vol. 86, No 14, pages 5517-5521	
\vdash		C41	Stanford et al. (1998). Expression Trapping: Identification of	
		C41	Novel Genes Expressed in Hematopoietic and Endothelial	\
			Lineages by Gene Trapping in ES cells. Blood, Vol. 92, No. 12,	
			pages 4622 to 4631.	
		C42	Kerr et al. (1996). Analysis of lipopolysaccharide-response genes	
			in B-lineage cells demonstrates that they can have differentiation	
			stage-restricted expression and contain SN2 domains. Proc. Natl.	
			Acad. Sci. Vol. 93, No. 9, pages 3947-3952.	
- \		C43	Tate et al. (1998). Capturing novel mouse genes encoding	
J	סד		chromosomal and other nuclear proteins. J. Cell. Science, Vol.	
<u> </u>			111, pages 2575-2585.	

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Examiner	/Jennifer Dunston/ (10/19/2006)	Date
Signature	/definiter Dunscon/ (10/13/2000)	Considered

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IN	FORMATI	ON DISCLOSURE	Application Number	10/660,893
		BY APPLICANT	Filing Date	September 12, 2003
			First Named Inventor	Charles Link
(use as many sheets as necessary)			Group Art Unit	1645 1636
		is as necessary)	Examiner Name	Yet to Be Assigned Dunston
Sheet	6	of 8 6	Attorney Docket Number	05237.0003.CPUS01

	C44 Suarez, et al. (1997). Green fluorescent protein-based reporter	
JD	systems for genetic analysis of bacteria including monocopy	Ç.
עט	applications. Gene, Vol. 196, Nos. 1-2, pages 69-74.	

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Signature	/ Jenniter Dunscon/ (10/19/2000)	Considered

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Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number. Subshullation Dim 1449/PTO Complete if Known **Application Number** 10/660,893 INFORMATION DISCLOSURE September 12, 2003 Filing Date STATEMENT BY APPLICANT First Named Inventor Charles J. Link (Use as many sheets as necessary) 1645 1636 Group Art Unit Examiner Name Not yet assigned Dunston Attorney Docket Number 05237.0003.CPUS01 Sheet Of 2

		U.S. P.	ATENT DOCU	MENTS	
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines,
Initials*	No. 1	Number – Kind Code ^{1 (1 known)} .	MM-DD-YYYY	Applicant of Cited Document	Where Relevant Passages or Relevant Figures Appear
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Examiner Initials*	Cite No.	Country Code ³ -Number ⁴ - Kind Code ⁵ (if known)	MM-DD- YYYY	Name of Patentee or Applicant of Cited Document	or Relevant Figures Appear	Τ°
JD	B4	WO 2004/065553	08/05/2004	Health Research, Inc.		

Examiner	1- 10 - 1 (10 10 10 10 10 10	Date
Signature	/Jennifer Dunston/ (10/19/2006)	Considered

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THE ORMATION DISCLOSURE	Application Number	10/660,893
STATEMENT BY APPLICANT	Filing Date	September 12, 2003
7 7005 2	First Named Inventor	Charles J. Link
JUH (Use as many sheets as necessary)	Group Art Unit	1645 1636
\d	Examiner Name	Not yet assigned Dunston
engerace 2 of 1 2	Attorney Docket Number	05237.0003.CPUS01

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JD	C45	International Search Report from PCT/US04/29658 dated May 17, 2005	

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Signature	/ Jennifer Bungeon, (1)	0/13/2000/	Considered	

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